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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,611	03/22/2004	Mary Collins	01997.043200	2470

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EXAMINER	
WANG, CHANG YU	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/806,611	COLLINS ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *May 23, 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19, 29-40, drawn to a method of treating multiple sclerosis in a subject comprising administering to the subject an agonist of IL-21/IL-21R, classified in class 514, subclass 2, for example.

II. Claims 20-26, drawn to a pharmaceutical composition comprising an IL-21/IL-21R agonist and an anti-inflammatory agent, classified in class 530, subclass 350, for example.

III. Claims 27-28, drawn to a pharmaceutical composition comprising an IL-21/IL-21R agonist and a protein that stimulates myelin basic protein, classified in class 530, subclass 350, for example.

IV. Claims 41-46, drawn to a method of evaluating treatment of multiple sclerosis in a subject comprising administering to the subject an agonist of IL-21/IL-21R, classified in class 436, subclass 174, for example.

V. Claims 47-49, drawn to a pharmaceutical composition comprising an IL-21 polypeptide, classified in class 530, subclass 350, for example.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions II and III, Inventions II and V, Inventions III and V are directed to related products The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious

variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the composition in the Group II encompasses an IL-21/IL-21R agonist and an anti-inflammatory agent, such as IFN-1α. The composition in the Group III encompasses an IL-21/IL-21R agonist and a protein that stimulates myelin basic protein, such as glatiramer acetate. Since the mechanisms/effects of anti-inflammatory agents are different from those of proteins stimulating myelin basic protein, the results/effects derived from these two compositions (Groups II and III) are distinct from each other. The composition of anti-inflammation agent in Group II and the protein that stimulates myelin basic protein in Group III are not required by Group V. Thus, Inventions II and III, Inventions II and V, Inventions III and V are patentably distinct.

3. Inventions I and IV are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the results and effects in the method of treatment (in Group I) are not necessarily the same as those in the method of evaluating the therapeutic effects (in Group IV). In addition, the materials and steps and equipments used in the method of Group IV are not required by Group I. Thus, Inventions I and IV are patentably distinct.

4. Inventions II and I, IV; Inventions III and I, IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process (Groups I and IV) for using the composition of Group II/III can be practiced with alternative nucleic acids, peptides, antibodies of other molecules. Thus, Inventions II and I, IV; Inventions III and I, IV are patentably distinct.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

6. This application contains claims directed to the following patentably distinct species of the claimed inventions:

i. If any one Group from Groups I-III is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of IL-21/IL-21R agonist selected from A) polypeptide or B) antibody as recited in claims 1, 20 and 27 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 20, 27 are generic.

ii. If Group I or Group II is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of anti-inflammatory agent selected from A) IFN-1a/b, B) TNF-antagonists, C) IL-12 antagonists, D) IL-23 antagonists, E) methotrexate, F) leflunomide, G) sirolimus (rapamycin), or H) CC1-779 as recited in claims 8 and 24 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 20 are generic.

7. The species listed above are patentably distinct for the following reasons:

These species are distinct because they are different molecules/compositions. Each specific species differs with respect to its composition, structural feature, function and use. The polypeptides and antibodies differ in structure and function as they are composed of divergent amino acids, and the use for each molecule is different. They are also differentially able to bind to other molecules or mediate other biological functions. In addition, the compositions and molecular mechanisms contributed to the action of each molecule listed in the group ii are very different and so are the effects. Thus, these species are patently distinct.

8. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-V and a single species from groups i-ii that are applicable as set forth above to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected group and species.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

14. Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday and every other Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW
August 7, 2006

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER